



## Global Product Development

10 May 2021

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**Re: Emergency Use Authorization (EUA) 27034**

**Pfizer-BioNTech COVID-19 Vaccine**

**Response to FDA 05 May 2021 Information Request**

Dear Dr. Gruber,

Reference is made to the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine for the active immunization to prevent COVID-19 in individuals  $\geq 16$  years of age and older issued on 11 December 2020. Further reference is made to the Amendment to the EUA submitted 09 April 2021 to extend the indication to 12 years of age.

Reference is also made to comments on the draft Healthcare Provider Factsheet/Full EUA Prescribing Information received from the Agency on 05 May 2021.

The following updated documents for the Healthcare Provider Factsheet/Full EUA Prescribing Information and complementary revision to the Recipient and Caregiver Fact Sheet are provided in Module 1.14.1:

For the Healthcare Provider Factsheet/Full EUA Prescribing Information:

- Track change ([Word](#))
- Annotated ([PDF](#))
- Clean copy ([PDF](#) and [Word](#))

For the Recipient and Caregiver Fact Sheet:

- Track change ([Word](#))
- Annotated ([PDF](#))

- Clean copy ([PDF](#) and [Word](#))

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at [neda.aghajanimemar@pfizer.com](mailto:neda.aghajanimemar@pfizer.com).

Sincerely,

Neda Aghajani Memar, Pharm.D.  
Director,  
Pfizer Global Regulatory Affairs

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CC: Michael Smith, Ph.D.